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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,315	10/23/2001	Hugh Semple Munro	740150/52050-C	9422

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NIXON PEABODY LLP
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101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/004,315

Applicant(s)

MUNRO ET AL.

Examiner

Sharmila S. Gollamudi

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-- Th MAILING DATE f this communication appears n the cover she t with th correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1-15 and 17-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

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DETAILED ACTION

Receipt of Extension of Time, Supplemental Information Disclosure, and Amendment A received on July 9, 2003 is acknowledged. Claims 1-15 and 17-44 are pending in this application. Claim 16 has been canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 29 recite PTFE, which is indefinite. It is unclear what exactly this stands for. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 12, 15, 17, 18, 21, 24-27, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/42985.

WO discloses a wound dressing and the method of making it. The method includes placing a gel mixture of polymers on a thin plastic film (web) and applying a foam layer (the perforated substrate) to the uncured gel mixture with the aid of a roller.

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The substrate and the gel are placed in the oven to cure the gel mixture. The gel coating should not block the pores of the substrate, thus the gel is applied in a thickness of 0.1-1 mm and the total gel layer has thickness of 0.2-2 mm. See page 9. The gel layer is a chemically cross-linked silicone gel (page 5).

Claims 23 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Brassington et al (4,838,253).

Brassington teaches a silicone coated permeable wound dressing (Abstract). The substrate is an apertured material, which is unoccluded by the gel (col. 5, lines 15-20).

*Note instant claims are product by process claims and even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8, 19, 22-23, 28-30, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42985 in view of Jensen (5,133,821).

WO discloses a wound dressing and the method of making it. The method includes placing a gel mixture of polymers on a thin plastic film (web) and applying a foam layer (the perforated substrate) to the uncured gel mixture with the aid of a roller.

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The substrate and the gel are placed in the oven to cure the gel mixture. The gel coating should not block the pores of the substrate, thus the gel is applied in a thickness of 0.1-1 mm and the total gel layer has thickness of 0.2-2 mm. See page 9. The gel layer is a chemically cross-linked silicone gel (page 5).

WO does not specify the type of plastic, or teach a coating on the plastic film, or a release sheet.

Jensen teaches a method of making wound dressing wherein the gel is placed between a release paper (coated web) and a substrate and extruded via a rolling process. Jensen teaches a release coating on one of its surfaces minimizes the friction generated during the rolling process. The reference teaches the preferred release web is silicone paper, which is removed after the rolling process. (Note col. 3, lines 53-65). Jensen also teaches a protective release covering which is removed upon use (Figure 3, 32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO 97/42985 and Jensen and substitute WO's plastic film for Jensen's material. One would be motivated to do so since Jensen teaches a release coating minimizes friction generated during the rolling process. Thus, since WO and Jensen utilize the same rolling process, one would be motivated to use a paper coated with silicone to increase efficacy during the process of making the dressing. Further, one would be motivated to look to Jensen since Jensen teaches a protective release paper before use of the dressing.

Respons to Arguments

Applicant argues that WO teaches away from lowering the surface energy web. It is argued that although WO teaches a range of options for preventing an excessively large number of pores from being occluded, none of these options relate to the construction of the underlying web. It is argued there is no motivation to modify the web. Applicant argues that Jensen uses a hydrocolloid adhesive.

First the examiner points out that the process claim does not recite that the web is used to prevent occlusion of the substrate pores; therefore the feature the applicant relies on is not a limitation of the claims. The instant claims are limited to a process of coating a perforated substrate without occlusion with a generic gel mixture and web. Therefore, WO meets this claim since a silicone polymer is taught with a plastic film. Inherently the plastic film has a lower surface energy than the liquid polymer mixture. Further, the examiner points out that the dependent claims recites that the web is made silicone, polyethylene, PTFE, which are types of low energy plastics. Jensen is solely relied upon for the web and not the gel mixture. The motivation to coat the web is that it prevents the gel from sticking to the roller. Thereby making the rolling process more efficient. The fact that applicant has a different reason to use the coating on the film as opposed to applicant is cannot be the basis for patentability when the differences would otherwise be obvious.

Claims 1-10, 12-31, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheong (5,352,508) in view of Jensen (5,133,821).

Cheong discloses a net wound dressing wherein a hydrophilic resin is coated on a substrate without occlusion (abstract). The resin is a polymerized hydrogel or

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crosslinked polyurethane resin (column 3). Suitable substrates are woven and non-woven materials such as polyamide, polypropylene, cotton, rayon, or wool (col. 5, lines 1-3). The amount of resin coated on the substrate is 25-300 g/m². The resin is applied to coating rollers and coated on to the substrate, which then undergoes heating to cure the resin (col. 5, lines 20-25 and example 5). In example 1, the reference teaches coating one side of the substrate.

Cheong does not teach a coated web.

Jensen teaches a method of making wound dressing wherein the gel is placed between a release paper (coated web) and a substrate and extruded via a rolling process. Jensen teaches a release coating on one of its surfaces minimizes the friction generated during the rolling process. The reference teaches the preferred release web is silicone paper which is removed after the rolling process. (Note col. 3, lines 53-65). Jensen also teaches a protective release covering which is removed upon use (Figure 3, 32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Cheong and Jensen. One would be motivated to do so since Jensen teaches a release coating minimizes friction generated during the rolling process. Thus, since Cheong and Jensen utilize the same rolling process, one would be motivated to use a paper coated with silicone to increase efficacy during the process of making the dressing. Further, Jensen teaches that the web prevents the gel from being transferred to the roller during manufacturing and Cheong discusses the problem of the resin sticking to the rollers on column 5.

Response to Arguments

Applicant argues that Cheong is considered with preventing an excessively large number of pores from being occluded, none of these options relate to the construction of the underlying web.

First the examiner points out that the process claim does not recite that the web is used to prevent occlusion of the substrate pores; therefore the feature the applicant relies on is not a limitation of the claims. The instant claims are limited to a process of coating a perforated substrate without occlusion with a generic gel mixture and web. Therefore, Cheong only lacks in the web. However, Cheong does present a problem of the resin sticking to the rollers. Therefore, one of ordinary skill in the art would look to Jensen to solve this problem. The motivation to coat the web is that it prevents the gel from sticking to the roller. Thereby making the rolling process more efficient. The fact that applicant has a different reason to use the coating on the film as opposed to applicant is cannot be the basis for patentability when the differences would otherwise be obvious.

Claims 11 and 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheong (5,352,508) in view of Jensen (5,133,821) in further view of Kundel (5,674,346).

As set forth above, Cheong and Jensen teach wound dressings and a process of making the wound dressing.

The references do not teach a gel containing acrylate monomer.

Kundel teaches a hydrogel wound dressing. Kundel teaches conventional polymers such as acrylates that form the hydrogel (col. 4, lines 30-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cheong and Kundel since both teach hydrophilic wound dressings. One would be motivated to look to Kundel since the reference teaches the conventional use of acrylates in wound dressing compositions. Therefore, it is deemed obvious to use conventional gel materials with the expectation of similar results.

Response to Arguments

Applicant argues that Kundel does not overcome the deficiency of Cheong and Kundel.

Applicant's arguments have been fully considered but they are not persuasive. The merits of Cheong and Jensen have been discussed above. Kundel is solely relied upon to teach the conventional use of acrylates in the wound dressing art.

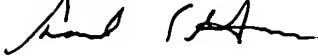
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

A handwritten signature in cursive script, appearing to read "Paul R. H. Am".A handwritten signature in cursive script, appearing to read "Thurman A. Page".

THURMAN A. PAGE
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 1600